

IMPORTANT INFORMATION ON THE MEDICAL DEVICE USER FEE RATES FOR FY 2006

AUGUST 2005

Dear Registered Establishment:

The Food and Drug Administration (FDA) is publishing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2006. The Federal Food, Drug, and Cosmetic Act (FD&C), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the Medical Device User Fee Stabilization Act of 2005 (MDUFSA) authorizes FDA to collect user fees for certain medical device applications. These fees apply to Premarket Approvals (PMAs), Product Development Protocols (PDPs), Premarket Reports (PMRs), Biologics Licensing Applications (BLAs for certain medical devices reviewed by FDA's Center for Biologics Evaluation and Research), some supplements, and Premarket Notifications [510(k)s].

The fee must be paid for the above listed applications, unless the applicant is eligible for a waiver or exemption. Small businesses may qualify for a waiver or a reduced fee.

Note: Important new information regarding the definition of a small business for FY2006 and 2007.

Firms with annual gross sales or receipts of \$30 million or less, including the gross sales and receipts of all affiliates, partners, and parent firms, may qualify for a fee waiver for their first PMA. Firms with annual gross sales or receipts of \$100 million or less, including the gross sales and receipts all affiliates, partners, and parent firms, may qualify for a reduced fee for all applications that are subject to a fee.

Payment must be received on or before the time the application is submitted. If the applicant has not paid all fees owed, FDA will consider the application incomplete and will not accept it for filing or review.

Fees for Premarket Notification [510(k)s]

For fiscal year 2006 (October 1, 2005 through September 30, 2006), the fee for 510(k) review is the following.

FY 2006 Device Review User Fees (U.S. Dollars)		
Application	Standard Fee	Small Business (≤\$100 million in gross receipts or sales) Fee
510(k)	\$3,833	\$3,066

The FY2006 fees apply to applications received on or after October 1, 2005. If the application and payment are received prior to October 1, 2005, applicants should pay the FY05 fee.

Do NOT send payment to FDA with your application. Additional information, including instructions on how and where to send payment and how to qualify as a small business, is available at <http://www.fda.gov/cdrh/devadvice/314a.html>.

This application fee applies to all 510(k)'s including Traditional, Abbreviated, and Special 510(k)s.

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Fees for Premarket Approvals

For fiscal year 2006 (October 1, 2005 through September 30, 2006), the fees for these applications are:

FY 2006 Device Review User Fees (U.S. Dollars)		
Application	Standard Fee	Small Business (≤\$100 million in gross receipts or sales) Fee
Premarket Application (PMA, PDP, BLA, PMR) NOTE: First premarket application from firms with gross receipts or sales ≤ \$30 million	\$259,600 Fee is waived	\$98,648
Panel-track Supplement	\$259,600	\$98,648
Efficacy Supplement (for BLA)	\$259,600	\$98,648
180-day Supplement	\$55,814	\$21,209
Real-time Supplement	\$18,691	\$7,103

The FY2006 fees apply to applications received on or after October 1, 2005. If the application and payment are received prior to October 1, 2005, applicants should pay the FY 05 fee.

Do NOT send payment to FDA with your application. Additional information, including instructions on how and where to send payment and how to qualify as a small business, is available at <http://www.fda.gov/cdrh/devadvice/pma/userfees.html>

Fees for FY 2007 and subsequent years will be published in the *Federal Register* 60 days before the start of each fiscal year.

The Division of Small Manufacturers, International and Consumer Assistance (DSMICA) can answer questions concerning the new law and help you find guidance documents and other reference materials. DSMICA can be contacted by phone at 800-638-2041 or 301-443-6597 or by email at DSMICA@CDRH.FDA.GOV. Questions regarding products regulated by the Center for Biologics Evaluation and Research should be directed to the Office of Communication, Training and Manufacturers Assistance (OCTMA). OCTMA can be contacted by phone at (301) 827-2000 or (800) 835-4709 or by email at MATT@CBER.FDA.GOV

Further information regarding FY2006 User Fees is available at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/05-15863.htm>, while additional information about the Medical Device User Fee and Modernization Act is available at: <http://www.fda.gov/cdrh/mdufma/index.html>.

Sincerely yours,

John F. Stigi
Director, DSMICA
Center for Devices and Radiological Health
U.S. Food and Drug Administration